

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Transmissible Spongiform Encephalopathies (TSE) Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

DMB

Display Date	5-4-00
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Certifier	SWRESE

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Transmissible Spongiform Encephalopathies (TSE) Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on June 1, 2000, 8:30 a.m. to 5:30 p.m. and on June 2, 2000, 8:30 a.m. to 3:30 p.m.

Location: Holiday Inn, Ballroom II, Montgomery Village Ave., Gaithersburg, MD.

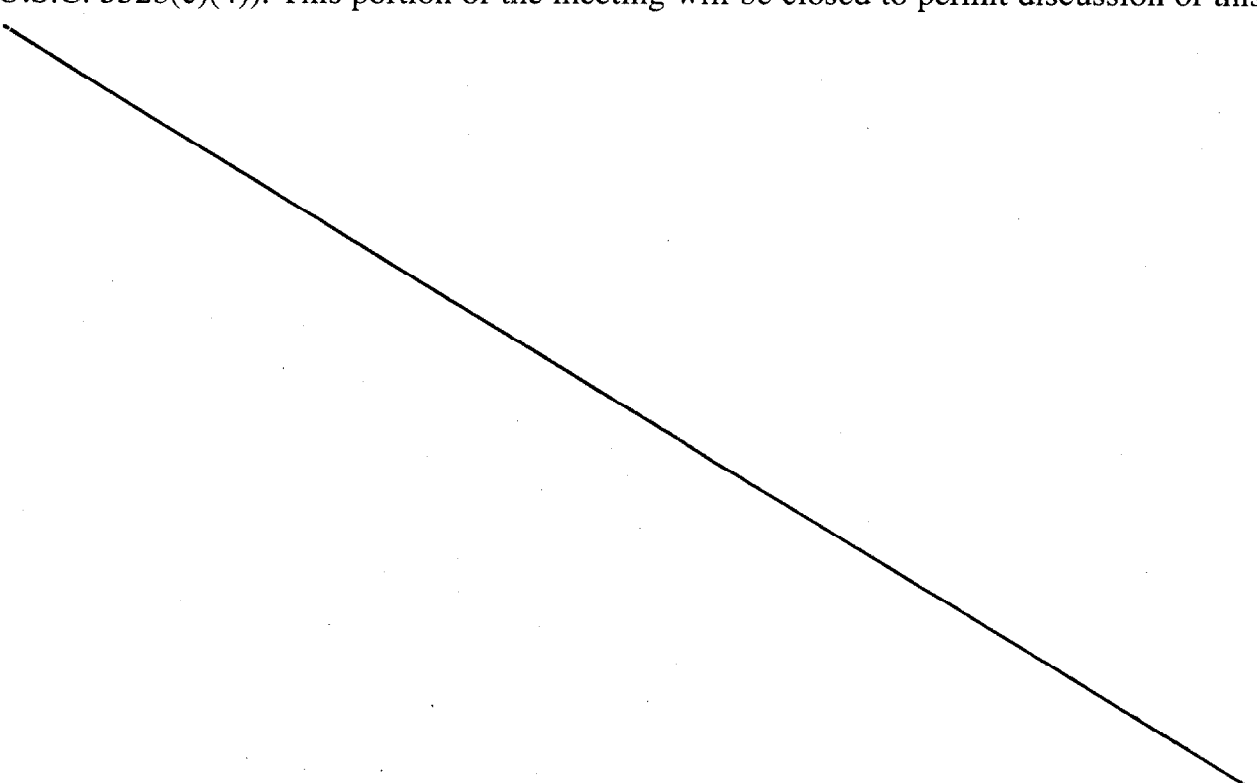
Contact Person: William Freas, or Sheila D. Langford, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-0314, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12392. Please call the Information Line for up-to-date information on this meeting.

Agenda: On June 1, 2000, the committee will discuss policies for deferral of blood and plasma donors because of their possible exposure to the agent of bovine spongiform encephalopathy (BSE). On June 2, 2000, the committee will discuss the scientific merit of leukoreduction as a method to reduce the theoretical risk of Creutzfeldt-Jakob Disease (CJD) and/or new variant CJD (nvCJD) in blood and blood components for transfusions as well as plasma for manufacture into derivatives.

In the afternoon, the committee will receive an update on the regulatory status of human dura mater.

Procedure: On June 1, 2000, from 8:30 a.m. to 5 p.m. and June 2, 2000, from 8:30 a.m. to 3:30 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by May 15, 2000. Oral presentations from the public will be scheduled between approximately 8:30 a.m. to 9 a.m. and 1 p.m. to 1:30 p.m. on June 1, 2000, and between 8:30 a.m. to 9 a.m., and 1 p.m. to 1:30 p.m. on June 2, 2000. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 22, 2000, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On June 1, 2000, from 5 p.m. to 5:30 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). This portion of the meeting will be closed to permit discussion of this material.



Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.

2).

Dated: 4/21/00
April 21, 2000



Linda A. Suydam
Senior Associate Commissioner

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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